K023521

NOV 1 9 2002

510(k) SUMMARY

Berkline Corporation's
Model LC Series Lift Out Chairs

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Berkline Corporation
One Berkline Drive
Morristown, TN 37813
Phone: (423) 585-1500
Facsimile: (423) 585- 1760

Contact Person: David Popkin
Senior Vice President, Legal services

Date Prepared: September 24, 2002

Name of Device and Name/Address of Sponsor

Model Easy Lift Series Lift Out Chairs

Berkline Corporation
One Berkline Drive
Morristown, Tennessee
Phone: (423) 585- 1500
Facsimile: (423) 5856- 1760

Common or Usual Name

Lift Out Chair

Classification Name

Chair, Electric, Positioning

Predicate Devices

Pride Health Care Inc. TMR48 Lift Chair (K953342) and Invacare Model LC Lift Chair (K002171).

Intended Use

The intended use of the Berkline Model Easy Lift Series Lift Out Chair to assist persons who have difficulty rising from a seated position to a standing position.

Technological Characteristics and Substantial Equivalence

A. Device Description

The Berkline Model LC Series Lift Chairs are electrically powered, motor driven devices designed for use in the home or an extended care environment. Their intended function and use is to raise persons from a seated position to a standing position. They are designed for use by elderly or physically challenged individuals who have difficulty rising to a standing position once seated.

The chairs are consist primarily of welded steel frame, an upholstered chair assembly, and motorized lift actuator. A hand held pendant type control is used activate the drive motor and raise or lower the chair to the desired position. Model numbers and physical dimensions vary with the type of aesthetic style of the chair.

B. Substantial Equivalence

The Berkline Model LC Series Lift Out Chairs are substantially equivalent to Pride Health Care Inc. TMR48 Lift Chair (K953342) and Invacare Corporation Model LC Series Lift Chair (K002171). Each of these products are electrically powered, motor driven, lift out chairs with the same intended function and use which is to assist elderly and/or physically challenged persons to arise from a seated position to a standing position.

PERFORMANCE DATA

The Berkline Model LC Lift Chairs have been tested to and meet:

- U.L. 1647 "Standard for Motor-Operated Massage and Exercise Machines".
- U.L. 73 "Standard for Motor Operated Appliances"

The upholstery used has been tested to and meets:

- California TB 117 (Flammability)
- UFAC Fabric Classification (Class I)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 9 2002

Berkline Corporation
David Popkin
Senior Vice President, Legal Services
One Berkline Drive
Morristown, Tennessee 37813

Re: K023521
Trade/Device Name: Easy Life Lift Chair
Regulation Number: 890.3110
Regulation Name: Electric positioning chair
Regulatory Class: Class II
Product Code: INO
Dated: October 1, 2002
Received: October 21, 2002

Dear Mr. Popkin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

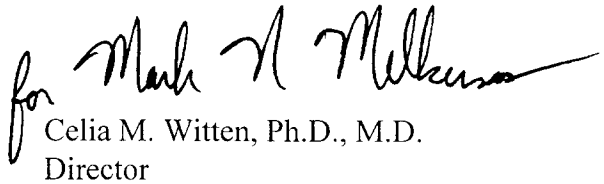
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): *TBD*

Device Name: Berkline LLC Easy Lift Electric Positioning Chair

Indications For Use: The intended use of the Berkline Model Easy Lift Series Lift Out Chair to assist persons, who have difficulty rising from a seated position to a standing position.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ✓

for Mark N Milhern
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(Optional Format 1-2-96)

K023521